

REMARKS

Claims 42, 44-52, 55 and 57-80, and 83-87 are pending.

Claims 1-41, 43, 53-54, 56, 81-82, and 88-188 have been canceled.

Claim 78 is currently amended.

Reconsideration of the application is requested.

§ 112 Rejections

Claim 78 was rejected under 35 USC § 112, first paragraph, as failing to comply with the enablement requirement.

Claim 78 has been amended to remove the language regarding solvates, since the claims would still cover solvated (and any other crystal forms of) the drug or drug salt.

Claims 42, 44-52, 55 and 57-87 were rejected under 35 USC § 112, second paragraph, as being indefinite due to the language “discrete, nonfilm-forming particles” in claim 42.

Applicants respectfully traverse for the following reasons. First, while the Office Action alleges that EP 0521455 A2 is evidence that the claimed polymers are known in the art as film-forming polymers, this does not mean the language “discrete, nonfilm-forming particles” is unclear or indefinite. Since the issue is clarity of language, not enablement, it is submitted that prior art teaching away from the invention does not render otherwise clear language regarding that characteristic unclear or indefinite. Moreover, while EP ‘455 is correct that such polymers can be film-forming, it is clear throughout the present application disclosure that such physical characteristics are determined by selection of polymer chain length and polydispersity.

Second, and more importantly, one of ordinary skill in the art would find the language “discrete, nonfilm-forming particles” abundantly clear. The fact that EP 0521455 A2 refers to film-forming implicitly acknowledges that the language used to refer to this characteristic is used and understood by those skilled in the art and, thus, describing something as “nonfilm-forming” is also clear.

§ 103 Rejections

Claims 42, 44-52, 55, 57-87 were rejected under 35 USC § 103(a) as being unpatentable over Duan et al. (WO 94/21229) as evidenced by Takeda et al. (US Patent 6117455).

Applicants respectfully traverse. A *prima facie* showing of obviousness has not been established because (a) the asserted combination of Duan et al. and Takeda et al. fails to disclose each element of the claimed invention, and (b) there has been no reasonable explanation of a motivation to modify Duan et al. and/or Takeda et al. to arrive at the claimed invention (i.e., the assertion of a motivation is merely conclusory).

Specifically, an important limitation of the presently claimed invention set forth in independent claim 42 is that (underlining added):

“... a sufficient amount of a biocompatible polymer, at least four times the amount of drug on a weight to weight basis, dissolved in the formulation so as to provide for sustained release of the drug;

Duan et al. does not in fact disclose or suggest any formulation where the amount of biocompatible polymer is four times the amount of drug. Duan et al. merely discloses a range of

drug concentrations and a range of polymer concentrations that could in theory arrive at a 4:1 polymer drug ratio only using impermissible hindsight based on the present application disclosure. Duan et al. discloses the use of biocompatible polymer as a “dispersing aid” which one skilled in the art would normally regard as suggesting a smaller amount of dispersing aid (polymer) to drug. A *prima facie* showing of obviousness cannot be established where a key limitation of the claims is not disclosed.

Further, Duan et al. provides no disclosure or suggestion of using biocompatible polymer so as to provide sustained release of drug. This is a different benefit than use as a dispersing aid, and without knowing of such benefit there would have been no motivation whatsoever to use a much larger ratio of polymer to drug. The skilled medicinal aerosol formulator would not have used an unnecessary excess of a dispersing aid polymer unless there was a particular reason to do so. Here, the only reason to do so is to provide sustained release, which is a key element of the claimed invention completely absent in Duan et al.

Interestingly, the observation made by the Examiner regarding EP 0521455 A2 actually teaches away from the present invention because inhaled drug particles would not be suitable if they were film-forming because they would tend to either coat the lung or agglomerate during aerosolization which would make the too large to reach the lungs. It was a surprising result of the invention that relatively large biocompatible polymer to drug ratios could be used in an aerosol formulation and still have discrete, nonfilm-forming particles.

Accordingly, for the above reasons, there is no *prima facie* showing of obviousness as to the present claims.

Obviousness-Type Double Patenting

Claims 42, 44-52, 55 and 57-87 were rejected on the ground of obviousness-type double patenting over claims 1-36 and 39-41 of U.S. Patent No. 5569450 in view of Duan et al. (WO 94/21229). Applicants respectfully traverses.

Since neither the claims of the ‘450 patent nor the disclosure of Duan et al. actually disclose or suggest use of at least four times more polymer than drug in order to provide sustained release, Applicants respectfully submit there is no obviousness-type double patenting. All of the reasons explained above apply to this double-patenting rejection as well—i.e.,

obviousness is not established where the prior art relied upon fails to disclose both the ratio of polymer to drug being claimed and the reason to use such increased amounts of polymer.

Claims 42, 44-52, 55 and 57-87 were rejected on the ground of obviousness-type double patenting over claims 1-19 of U.S. Patent No. 5725841 in view of Duan et al.

Since neither the claims of the '841 patent nor the disclosure of Duan et al. actually disclose or suggest use of at least four times more polymer than drug in order to provide sustained release, Applicants respectfully submit there is no obviousness-type double patenting. All of the reasons explained above apply to this double-patenting rejection as well—i.e., obviousness is not established where the prior art relied upon fails to disclose both the ratio of polymer to drug being claimed and the reason to use such increased amounts of polymer.

Claims 42, 44-52, 55 and 57-87 were provisionally rejected on the ground of obviousness-type double patenting over claims 1-30 and 33 of copending application No. 11816883 in view of Duan et al.

Since neither the claims of the '883 application nor the disclosure of Duan et al. actually disclose or suggest use of at least four times more polymer than drug in order to provide sustained release, Applicants respectfully submit there is no obviousness-type double patenting. All of the reasons explained above apply to this double-patenting rejection as well—i.e., obviousness is not established where the prior art relied upon fails to disclose both the ratio of polymer to drug being claimed and the reason to use such increased amounts of polymer.

In view of the above, it is submitted that the application is in condition for allowance.
Examination and reconsideration of the application as amended is requested.

Respectfully submitted,

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